ClinicalTrials.gov
Protocol Registration System
User's Guide for NIMH Investigators
December 2002

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National Institute of Mental Health (NIMH)
Overview

What is *ClinicalTrials.gov*?

ClinicalTrials.gov provides patients, family members, health care professionals, and members of the public easy access to information on clinical trials for a wide range of diseases and conditions. The U.S. National Library of Medicine (NLM) has developed this site in collaboration with all NIH Institutes and the Food and Drug Administration (FDA).

What is the Protocol Registration System (PRS)?

The Protocol Registration System (PRS) is a Web-based tool developed for submitting clinical trials information to *ClinicalTrials.gov*. Records submitted through PRS (http://register.clinicaltrials.gov) are available to the public at *ClinicalTrials.gov*. PRS users enter information about their clinical trials, ensure that the information is correct, and easily understood by members of the public, and update it in a timely manner. The *ClinicalTrials.gov* team maintains PRS and the *ClinicalTrials.gov* site and may make minor corrections to trial records.

NIH and NIMH are firmly committed to their mission of improving the lives and health of the public. Through research all people can benefit from the knowledge compiled through testing medications, procedures, vaccines, behaviors, and devices from clinical trials.

Administrative Procedures

User Definitions:

NIMH *ClinicalTrials.gov* Liaison (Nancy Oleksa, e-mail: noleksa@mail.nih.gov)
NIMH Contractor (Christine Love, e-mail: update@clinicaltrials.gov)
PRS User

Process:

1. NIMH Liaison alerts NIMH Contractor of a new grantee.

2. Using the grant as the source, NIMH Contractor creates a skeleton record for the clinical trial by completing the following fields:

   Grant Number/Unique Protocol ID
   Official Title
   Sponsoring Organization

3. NIMH Contractor contacts the User (Attachment 1), and requests the User to complete remaining data fields.

4. The User logs into PRS and completes the record following the PRS Data Element Definitions (Attachment 2), providing data for the following mandatory fields:

   Brief Title
   IND Protocol
   IND Grantor (if applicable)
   IND Number (if applicable)
   Brief Summary
   Detailed Description
   Study Phase
   Study Type
   Overall Study Status
   Study Design
   Intervention Type
   Intervention Name
   Condition(s)
   Eligibility Criteria
   Gender
   Age Limits
   Accepts Healthy Volunteers?
   Contact Information

5. User changes record status to [Complete] and the PRS automatically notifies the NIMH Liaison.

6. NIMH Liaison reviews and approves, and releases record to *ClinicalTrials.gov*.

7. NLM publishes the record within 2-5 days of release.

Please note: Records are not released until all data have been reviewed. NIMH reserves the right to edit data entered by the User.

PRS User Responsibilities

PRS users provide and maintain information about their clinical trials by entering information into PRS, ensuring that the information is correct and easy to understand, and updated in a timely manner.

Through PRS, a user may:

Log-in to *ClinicalTrials.gov*.

Enter information regarding clinical trials.

Modify a record.

View a record.

Change a password.

Preview a record as a *ClinicalTrials.gov* page.

Complete and submit the trial data for approval.

Procedures for PRS Users

Logging In and Out of PRS:

1. Go to http://register.Clinicaltrials.gov to enter PRS.

2. Complete the three log-in fields
   A. Organization: NIMH
   B. User name: user login name*
   C. Password: user password (case-sensitive)*

3. Click [Login] and to get to the **Main Menu** of PRS.

4. To log out of PRS, select [Logout] from the **Main Menu** screen.

* *If this is your first time entering the system, contact the NIMH Liaison for a user name and password. For security reasons, users are asked to please change their password after logging in the first time.*

Creating a Record:

1. Click [Create] from the **Main Menu** screen.

2. Enter the Unique Protcol ID and Brief Title for your record on the **Create New Protocol Record** screen.

3. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.

4. After clicking [Continue] on the final data entry screen, click [OK] on the **Study Completed** screen.

Tips:

The data entry screens contain text boxes, radio buttons, pull down menus, and other tools to facilitate data entry.

Data screens are clustered by topic for each clinical trial. These include: Title, Sponsor, Summary, Status, Design, Interventions, Conditions, Eligibility, Locations, Citations, and Links.

Field definitions and examples can be viewed by clicking on the links associated with each field name.

The Conditions field requires the user to access a subject headings browser to data enter standard terms. If users cannot find the terms or choose not to use the browser, please enter the terms in the Keyword field. The NIMH Liaison will then search the subject browser and select relevant terms for the Conditions field, subject to approval.

A record may be completed during a single session or modified and saved for completion during later sessions.

Modifying Records:

1. Click [Modify] on the **Main Menu**.

2. Click [Edit] next to the record to be modified on the **Select Protocol Record-Edit** screen.

3. Locate the data field to be modified on the Edit Protocol Screen.

4. Click on the corresponding [Edit] for that field and make changes.

5. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.

6. After clicking [Continue] on the final data entry screen (**Links**), click [OK] on the **Study Completed** screen.

Viewing Records:

1. Click [View] on the **Main Menu**.

2. Click [View] next to record to be displayed on the **Select Protocol Record** – View screen.

3. **View Protocol Record** is read-only. User must choose Edit from the Main Menu to modify record information.

Previewing Records as They Appear on *ClinicalTrials.gov:*

1. Click [Modify] on the **Main Menu**.

2. Click [Edit] next to the record to be previewed

3. Click [Preview] to see the record displayed similar to how it appears on *ClinicalTrials.gov.*

4. Click [Continue] to return to the **Edit Protocol Record** screen.

Changing Your Password:

1. Click [Change password] on the **Main Menu**.

2. Enter:
   Old password*
   New password
   New password again for verification

3. Click [Change Password] to save new password.

*Contact Nancy if the password is forgotten or lost.

Completing and Submitting the Trial for Approval:

1. If modifying an existing record, click [Modify] from the **Main Menu**, then click the Edit link to the left of the record you wish to complete.

2. Proceed to the **Edit Protocol** Screen.

3. PRS automatically checks the data for any errors or potential problems. There are two types of messages that may be displayed for fields in the record:
   A. Error: a problem has been found with the record that MUST be corrected. The record will not be released to *ClinicalTrials.gov* until the error is resolved.
   B. Note: a potential problem has been found, that should be reviewed. The record can be released to *ClinicalTrials.gov* with a "Note."

4. After all available information has been entered into a record and there are no errors :
   A. Click on the [Change Status] link or the record.
   B. Click the Completed check box on the screen (this will generate an email to the NIMH Liaison).
   C. Type any comments in the text that you wish to have the NIMH Liaison review when viewing the record.
   D. Click [OK] to save the status change, or [Cancel] to retain the original status.

The NIMH Liaison will then review the clinical trial record. If no changes are needed, the record will be approved and sent to *ClinicalTrials.gov*.

Attachment 1: Sample PI Contact E-Mail

Dear Dr. Smith,

We are assisting the National Institute of Mental Health (NIMH) in adding descriptions of their clinical trials to *ClincialTrials.gov*—an Internet-based database maintained by the National Library of Medicine.

NIMH has identified your trial, "Depression in Kalamazoo" (grant number RX 5731), for entry into *ClinicalTrials.gov*. Please provide information on your trial by logging into the Protocol Registration System and following these instructions:

1. Visit this web site: https://register.clinicaltrials.gov
2. Log in with the following information:
   Organization: NIMH
   User Name: smith2
   Password: smith2
3. From the Main Menu screen, select Modify.
4. In the Search box, choose "Protocol ID" and key in "NH 072".
5. Select Edit.
6. Please provide as much information as possible in the available fields. Directions and further information are available by clicking on the field name. You might also find the "User's Guide" helpful in navigating through the system: http://www.nimh.nih.gov/studies/ctgovuserguide.pdf

Please e-mail me once you have completed entering your information, so that I can release your record to *ClinicalTrials.gov*. If you need any additional assistance, please e-mail or call me.

Sincerely,
Christine Love
National Library of Medicine's Clinical Information Services
301.519.5683

Attachment 2: Data Element Definitions

1. Titles and Background Information

Organization's Unique Protocol ID
Submission: Required
Definition: Identification number assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number. Grants with a prefix of P50 indicate a project that may contain many sub-projects where maybe two of which (say 2 & 5) involve human subjects of clinical trials.
Example: IA0014; MH42931A

Secondary IDs
Submission: Optional
Definition: Other identification numbers assigned to the protocol, including any applicable NIH grant numbers. Provide up to 5 Secondary ID Numbers. Example: 5 R01-MH42931A; MH56224

Brief Title
Submission: Required
Definition: Protocol title intended for the lay public, usually found on line one of the grant application.
Example: Preventing the Return of Depression in Elderly Patients

Official Title
Submission: Optional
Definition: Official name of the protocol provided by the principal investigator or sponsor.
Example: Maintenance Therapies in Late-Life Depression

Additional Information

IRB Approved?
Definition: Indicate if the protocol has received Institutional Review Board (IRB) approval. Select Yes/No.

Medicare: Organization is Deemed?
Definition: Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA, trials conducted at NCI cancer centers, and all trials of patients that are either conducted under an Investigational New Drug Application (IND) or are exempt from having an IND under 21 CFR 312.2(b)(1) are considered Medicare deemed. See Medicare Coverage Policy ~ Clinical Trials: Final National Coverage Decision.

Medicare: Study Meets Requirements?
Definition: The subject of the trial must evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage. See Medicare Coverage Policy ~ Clinical Trials: Final National Coverage Decision.

2. Investigational New Drug Application (IND) Information: Complete the following only if the protocol requires and Investigational New Drug Application (IND). (*Will not be made public- for administrative purposes only*.)

IND Protocol?
Submission: Required
Definition: Indicate if the protocol is being conducted under an Investigational New Drug Application (IND). If not, select "No" and continue. (*Will not be made public- for administrative purposes only*.)

IND Grantor
Submission: Required
Definition: FDA center to which the IND was submitted, i.e., Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER). Select one. (*Will not be made public- for administrative purposes only*.)

IND Number
Submission: Required
Definition: Number assigned to an Investigational New Drug Application (IND). If not yet received, use "Not Yet Assigned". (*Will not be made public- for administrative purposes only*.)
Example: 58-484

3. Sponsors

Sponsor
Submission: Required
Definition: Name of sponsoring organization who takes responsibility for and initiates a clinical investigation. In the case of NIMH grantees, the National Institute of Mental Health will always be the sponsor.
Example: National Institute of Mental Health (NIMH)

Collaborators
Submission: Optional
Definition: Full names of other NIH institutes or Federal agencies co-sponsoring and/or providing financial support for the protocol. Non-governmental institutions serving as trial sites should be listed as locations, not as collaborators. Provide up to 10 full names of collaborating organizations.

4. Study Description

Brief Summary
Submission: Required
Definition: Short description of the purpose of the protocol intended for the lay public.
Example: The purpose of this study is to assess the effectiveness and safety of both St. John's Wort and citalopram, each compared to a placebo, for the treatment of minor depression.

Detailed Description
Submission: Optional
Definition: Technical description of the protocol for health professionals, including information such as methodology and rationale, not already contained in other fields.
Example: Minor depression is highly prevalent, causes substantial morbidity and disability, presents a serious risk factor for the development of major depressive disorder, yet is under recognized and under treated. Researchers have determined that patients with minor depression frequently seek treatment from general practioners and are often treated with prescription antidepressants. There is a need to

evaluate the effectiveness of St. John's Wort in the management of minor depression. If the proposed study demonstrates the efficacy of St. John's Wort and/or citalopram, it will suggest treatment paradigms that can be tested and applied in primary care settings. At Screen Visit, Week 12, and Week 20, patients undergo a complete blood count with differential and other routine laboratory tests. Patients who meet screening criteria enter a 2-week washout period (or for fluoxetine, a 4-week washout period) during which no psychotropic medication is permitted. Participants are assigned randomly to one of three treatment arms in which St. John'sWort, citalopram, or placebo is given for a 12-week acute treatment phase. Participants are seen at screening, during the washout period, at baseline, and every 2 weeks thereafter for the course of the study. Participants that meet criteria for response (50 percent or greater reduction in Inventory for Depressive Symptoms - Clinicians [IDS-C]) at Week 12 continue to take their originally assigned double-blind medication for up to 26 weeks. At Week 12, nonresponders to placebo are crossed over to one of the two active treatments. Patients who remain nonresponders to that active treatment are crossed over to the alternative active treatment, with the investigator maintaining blind status.

5. Status

Study Phase
Submission: Required
Definition: Phase of the Investigation. Select only one.

Phase 1: includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include health participants and/or patients

Phase 1/Phase 2

Phase 2: includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under the study and to determine the common short-term effects and risks

Phase 2/Phase 3

Phase 3: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physical labeling

Phase 4: post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use

N/A: IND studies must not use this option

Study Type
Submission: Required
Definition: Nature of the investigation. Select one.

- Interventional: experimental studies in humans to investigate the safety and/or efficacy of a drug, gene therapy, vaccine, behavior, device, or procedure.
- Observational: studies in humans that record specific events occurring in a defined population without any intervention by the researcher, such as natural history, screening, and psychosocial studies.

Overall Study Status
Submission: Required

Definition: Overall protocol accrual activity for the protocol. Select one.

- Not yet recruiting: the protocol is not yet ret recruiting and enrolling participants
- Recruiting: the protocol is actively recruiting and enrolling participants
- No longer recruiting: the protocol is not recruiting or enrolling participants
- Complete: the protocol is no longer recruiting. Data analysis is complete.
- Suspended: recruiting or enrolling participants has halted but may potentially resume
- Terminated: recruiting or enrolling participants has halted and will not resume

Verification Date
Submission: Required
Definition: Date the protocol information, including status, was verified, whether changes or made or not.

Start Date
Submission: Optional
Definition: Date that the protocol begins.

Completion Date
Submission: Optional
Definition: Expected or actual completion date of the protocol.

6. Study Design

Study Type (Interventional)
Submission: Required
Definition: Primary investigative techniques used in the protocol. Select the most appropriate term describing the protocol from each of six categories: Purpose, Allocation, Masking, Control, Assignment, and Endpoint.

Purpose: reason for the protocol

- **Treatment:** protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition
- **Prevention:** protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition
- **Diagnosis:** protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition
- **Educational/Counseling/Training:** protocol designed to assess one or more interventions in an educational, counseling, or training environment

Allocation: participant selection

- Randomized Controlled Trial: participants are assigned to intervention groups by chance
- Nonrandomized Trial: participants are expressly assigned to intervention groups

Masking: knowledge of intervention assignments

- Open: no masking is used. All involved know the identity of the intervention assignment
- Single Blind: participants are unaware of the intervention assignment; investigators are aware.
- Double Blind: both participants and investigator s are unaware of the intervention assignment

Control: the nature of the intervention control

- Placebo: participants may receive **placebo only throughout** the course of the protocol
- Active: participants may receive some form of treatment (e.g., standard treatment) in place of the intervention under investigation
- None: no controls are used
- Historical: the control consists of results from past studies
- Dose Comparison: participants may receive one of several doses of the intervention

Assignment: intervention assignments
- Single or Group: all participants receive the **same** intervention throughout the protocol
- Parallel: participants receive **some** intervention throughout the protocol
- Cross-over: participants may receive **different** interventions sequentially during the protocol
- Factorial: participants may receive no intervention, **some** intervention, or **multiple** interventions **simultaneously**

Endpoint: overall outcome that the protocol is designed to evaluate. Select one.
- Safety: shows the drug is safe under conditions or proposed use.
- Efficacy: measure of an intervention's influence on a disease or health condition.
- Safety/Efficacy
- Bio-equivalence: scientific basis for comparing generic and brand name drugs.
- Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body
- Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound
- Pharmacokinetics: action of drugs in living systems
- Pharmacokinetics/Pharmacodynamics

Study Type (Observational)
Definition: Primary investigative techniques used in an observational protocol. Select the **most appropriate** term describing the protocol from each of the four categories:
Purpose, Duration, Selection, and Timing

Purpose: reason for the protocol
- Natural History: protocol designed to investigate a disease or condition through observation under natural conditions (i.e., without intervention)
- Screening: protocol designed to assess or examine persons or groups in a systematic way to identify specific markers or characteristics (e.g., for eligibility for further evaluation)
- Psychosocial: protocol designed to observe the psychosocial impact of natural events

Duration: length of protocol
- Longitudinal: studies in which participants are evaluated over long periods of
- time, typically months or years
- Cross-sectional: studies in which participants are evaluated over short periods
- of time, typically up to 10 weeks

Selection: sample selection
- Convenience Sample; participants or populations are selected due to ease of recruitment
- Defined Population: participants or populations are selected based on predefined criteria
- Random Sample: participants or populations are selected by chance

- Case Control: participants or populations are selected to match the control participants or populations in all relevant factors excepts for the disease; only the participants or populations have the disease

Timing: time of protocol
- Retrospective: a protocol that observes events in the past
- Prospective: a protocol that observed events in real time (may occur in the future)
- Both: a protocol that combined retrospective and prospective observation

7. Interventions

Submission: Required
Definitions: Primary interventions being studied. Provide specific name and type for each intervention (up to 10 items).

Intervention Type: select one per intervention
-Drug
-Gene Transfer- including gene transfer and recombinant DNA
-Vaccine
-Behavior
-Device
-Procedure

Intervention Name
Definition: generic name of the precise intervention being studies.
Examples:
Zidovudine (drug)
Exercise (behavior)

8. Conditions and Keywords

Conditions
Submission: Required
Definition: Primary diseases or conditions being studies, using the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary. The conditions are used to index studies in *ClinicalTrials.gov.* Select up to five disease or condition terms from the following MeSH categories: Diseases (c), Behavior and Behavior Modification (F01), and Mental Disorders (F03).

Keywords
Submission: Optional
Definition: Words or phrases that best describe the protocol. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

9. Eligibility

Eligibility Criteria
Submission: Required
Definition: Summary criteria for participant selection
Example:
Inclusion Criteria:
- Clinical diagnosis of Alzheimer's Disease
- Must be able to swallow tablets

Exclusion Criteria:

- Current alcohol or drug abuse
- Thyroid disease

Gender
Submission: Required
Definition: Physical gender of individuals who may participate in the protocol. Select one.

- Both: both female and male participants are being studied
- Female: only female participants are being studied
- Male: only male participants are being studied

Age Limits

Minimum Age
Submission: Required
Definition: Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours, or minutes). Select "N/A (No limit)" if no minimum age is indicated.

Maximum Age
Submission: Required
Definition: Maximum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours, or minutes). Select "N/A (No limit)" if no maximum age is indicated.

Acceptable Participants

Accepts Healthy Volunteers?
Submission: Required
Definition : Indicate if persons who have not had the condition(s) being studied or o Otherwise related conditions or symptoms, as specified in the eligibility requirements, May participate in the study. Select Yes/No.

Accepts Patients?
Definition: Indicate if persons who have or had the condition(s) being studies or otherwise specified in the eligibility requirements (e.g., specific symptoms), may participate in the study. Select Yes/No.

Expected Total Enrollment
Submission: Optional
Definition: Estimated number of participants to be studied

10. Protocol Location, Contact and Investigator Information

Multiple locations may be specified. Location is composed of the following fields:

Facility
Submission: Required
-Name: Full name of the organization where the protocol is being conducted
Examples: UCLA Eye Institute; Springfield Memorial Hospital
-City
-State/Province
-Postal Code
-Country

Recruitment Status: protocol accrual activity at the facility. Select one.
Submission: Required (if Overall Status is "Recruiting")

- Not yet recruiting: participants are not yet being recruited or enrolled
- Recruiting: participants are currently being recruited or enrolled
- No longer recruiting: participants are no longer being recruited or enrolled
- Completed: participants are no longer being recruited; data analysis is complete
- Suspended: recruiting or enrolling participants has halted but potentially will resume
- Terminated: recruiting or enrolling participants has halted and will not resume

Facility Contact
Submission: Required (If Overall Status is recruiting)

- First Name
- Middle Name
- Last Name
- Degree
- Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the facility contact person

Facility Contact Backup
Submission: Optional
Definition: Person to contact if Facility Contact is not available (i.e., a second contact person).

Investigators (at the protocol location)
Submission: Optional

- First Name
- Middle Initial
- Last Name
- Degrees
- Role: Principal Investigator or Sub-Investigator (pick one)

Central Contact
Submission: Required (if a Facility Contact is not provided)
Definition: Person providing centralized, coordinated recruitment information for the entire study.

- First Name
- Middle Initial
- Last Name
- Degree
- Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the facility contact person

Central Contact Backup
Submission: Optional
Definition: Person to contact if Central Contact is not available.

Overall Study Officials
Submission: Optional
Definition: Person(s) responsible for the overall scientific leadership of the protocol.

- First Name
- Middle Initial

- Last Name
- Degree
- Official's Role: Position or function of the official. Select one (Study Chair/Study Director/Principal Investigator).
- Organizational Affiliation: Full name of the official's organization.

11. Related Information

References
Submission: Optional
Definition: Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (**PMID**) of an article or enter the full bibliographic citation.

MEDLINE PMID
Definition: unique PubMed Identifier (**PMID**) for the citation
Example: **PMID**: 12000823

Citation
Definition: bibliographic reference in **NLM's MEDLINE** format
Example: Apolone G, Mosconi P, La Vecchia C. Post-traumatic stress disorder. N Engl J Med. 2002 May 9;346(19):1495-8; discussion 1495-8.

Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD)

This study is currently recruiting patients.

Sponsored by
National Institute of Mental Health (NIMH)

Purpose

STEP-BD is the largest treatment study ever conducted for bipolar disorder. It is a long-term outpatient study (5 years) that aims to find out which treatments, or combinations of treatments, are most effective for treating episodes of depression and mania and for preventing recurrent episodes. In addition, the study will evaluate treatment effectiveness in terms of quality of life, adherence to treatment, ability to work, social functioning, and treatment cost-effectiveness. While many treatments are used currently for bipolar disorder, including medications and psychotherapies, doctors are uncertain which of these treatments or combination of treatments actually work best. Findings from STEP-BD will help improve the treatment standards used by doctors in everyday clinical practice.

Condition	Treatment or Intervention	Phase
Mood Disorders Affective Disorders, Psychotic Bipolar Disorder Cyclothymic Disorder	Drug: lithium Drug: valproate Drug: bupropion Drug: paroxetine Drug: lamotrigine Drug: risperidone Drug: inositol Drug: tranylcypromine Behavior: Cognitive Behavioral Therapy Behavior: Family-focused Therapy Behavior: Interpersonal and Social Rythyms Therapy	N/A

Study Type: Interventional
Study Design: Treatment, Randomized, Double Blind, Placebo Control

Official Title: Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD)

Further Study Details:

STEP-BD is evaluating all the best-practice treatment options used for bipolar disorder: mood-stabilizing medications, antidepressants, atypical antipsychotics, and psychosocial interventions - or "talk" therapies - including Cognitive Behavioral Therapy, Family-focused Therapy, Interpersonal and Social Rhythm Therapy, and Collaborative Care (psychoeducation).

There are two kinds of treatment "pathways" in STEP-BD, and participants may have the opportunity to take part in both. The medications and psychosocial interventions provided in these pathways are considered among the best choices of treatment for bipolar disorder in everyday clinical practice.

In the "Best Practice Pathway," participants are followed by a STEP-BD certified doctor and all treatment choices are individualized. Everyone enrolled in STEP-BD may participate in this pathway. Participants and their doctors work together to decide on the best treatment plans and to change these plans if needed. Also, anyone who wishes to stay on his or her current treatment upon entering STEP-BD may do so in this pathway. Adolescents and adults age 15 years and older may participate in the Best Practice Pathway.

For adults age 18 and older, another way to participate is in the STEP-BD "Randomized Care Pathways." Depending on their symptoms, participants may be offered treatment in one or more of these pathways during the course of the study. The participants remain on mood-stabilizing medication. However, because doctors are uncertain which of several treatment strategies work best for bipolar disorder, another medication and/or talk therapy may be added. Each Randomized Care Pathway involves a different set of these additional treatments.

Unlike in the Best Practice Pathway, the participants in the Randomized Care Pathways are randomly assigned to treatments. Also, in some cases, neither the participant nor the doctor will be told which of the different medications is being added. This is called a "double-blind" study and is done so that the medication effects can be evaluated objectively, without any unintended bias that may come from knowing what has been assigned. Participants will not be assigned medications that they have had bad reactions to in the past, that they are strongly opposed to, or that the doctor feels are unsuitable for them. The medication(s) participants may be randomly assigned to in the Randomized Care Pathways are free of charge. There are other treatment options for participants if they do not respond well to the treatment assigned to them. Also, participants may return to the Best Practice Pathway at any time. About 1,500 individuals will be enrolled in at least one Randomized Care Pathway during their period of participation in STEP-BD.

It is important to note that STEP-BD provides continuity of care. For example, if a participant starts out in the Best Practice Pathway and later chooses to enter one of the Randomized Care Pathways, he or she continues with the same STEP-BD doctor and treatment team. Then, after completing the Randomized Care Pathway, the participant may return to the Best Practice Pathway for ongoing, individually-tailored treatment.

Eligibility

Ages Eligible for Study: 15 Years - N/A, Genders Eligible for Study: Both Criteria

Inclusion Criteria: General Inclusion Criteria: (1) current age 15 or older (Best Practice Pathway) or 18 years or older (Randomized Care Pathways); (2) able to give informed consent for data to be harvested; (3) meet DSM-IV criteria for Bipolar I Disorder, Bipolar II Disorder, Bipolar Disorder NOS, or Cyclothymic Disorder; (4) undergo a complete standard evaluation including clinical interview, self ratings, and laboratory studies; (5) meet with Clinical Specialist as scheduled; (6) able to complete all Study Registry Forms within 3 months of registration.

Exclusion Criteria: General Exclusion Criteria: (1) unwilling or unable to adhere to basic study requirements (i.e., complete rating forms, or attend scheduled evaluations); (2) not competent to give informed consent in the opinion of the investigator (e.g., psychotic).

Participants will be asked to remain in the study for up to five years so that the investigators can document and evaluate long-term treatment outcome. Participants will meet with their STEP-BD psychiatrist for periodic evaluations and/or treatment adjustments during the course of the study, fill out various self-rating forms, and when applicable, participate in psychotherapy. One of the psychotherapy options, Family-Focused Therapy, will require participants and their families to attend counseling sessions together. Overall, the estimated amount of time required from participants in the study is 2 to 4 hours per month.

Expected Total Enrollment: 5000

Location and Contact Information

For more information, call toll-free: 1-866-240-3250 stepbd@mailcity.com

California

Stanford University School of Medicine, Stanford, California, 94305-5723, United States; Recruiting
Nathan Dieckman 650-498-4801
Terrence Ketter, M.D., Sub-Investigator

Colorado

University of Colorado, Colorado Psychiatric Health Clinical Investigation Center, Denver, Colorado, 80220, United States; Recruiting
Chad Morris, Ph.D. 303-315-9472
Michael Allen, M.D., Sub-Investigator
Marshall Thomas, M.D., Sub-Investigator
David Miklowitz, Ph.D., Sub-Investigator

Kentucky

University of Louisville School of Medicine, Louisville, Kentucky, 40292, United States; Recruiting
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More Information

Click here for more information about the study

Study ID Numbers N01MH80001
NLM Identifier NCT00012558
Date study started 1998-09; Date Study Completed 2003-09
Record last reviewed 2002-04

Bone Loss in Premenopausal Women with Depression

This study is currently recruiting patients.

Sponsored by
National Institute of Mental Health (NIMH)

Purpose

Depression may be a major risk factor for osteoporosis and abnormally elevated stress hormone levels may contribute to bone loss. Depression is associated with elevated stress hormone levels. This study will determine whether women with major depression lose bone mass at a faster rate than women without depression. This study will also determine if the drug alendronate (Fosamax) can maintain or increase bone mass in premenopausal women with major depression and osteoporosis. This 12-month study requires 6 visits at the National Institutes of Health Clinical Center in Bethesda, Md. Participants will receive psychiatric, medical, dietary and stress hormone evaluations, including bone mineral density measurements. Participants with depression and low bone mass will be randomly assigned to take either 70 mg of alendronate or a placebo (a look-alike tablet with no active medication) once a week. Alendronate works by reducing the activity of osteoclasts (cells that cause bone loss.) The Food and Drug Administration has approved alendronate for treating and preventing osteoporosis in postmenopausal women; its use in premenopausal women with low bone mass and major depression is considered investigational. They will also take calcium (500mg) and vitamin D (400IU) supplements. If participants are currently taking anti-depressant medications, they may continue to do so. Participants with depression and normal bone mass will be compared to a control group of healthy, premenopausal women with normal bone mass.

Condition	Phase
Depression Healthy Osteopenia Osteoporosis	Phase IV

MEDLINE*plus* related topics: Bone Diseases; Depression; Osteoporosis

Study Type: Interventional

Official Title: The P.O.W.E.R. STUDY (Premenopause, Osteopenia/Osteoporosis, Women, Alendronate, Depression)

Further Study Details: This is a 12-month study on the natural history of bone turn-over in depressed women, ages 21 to 45 unless postmenopausal, with normal bone mass, and the response to treatment with alendronate in depressed women, ages 21 to 45 unless postmenopausal, with low bone mass (as indicated by a bone mineral density (BMD) of minus 1.5 SD below peak bone mass at the spine and/or hip). Osteopenia is defined as a BMD at the spine and/or hip that is between minus 1.5 and minus 2.5 SD; osteoporosis is defined as a BMD that is below minus 2.5 SD at the spine and/or hip. During the initial screening, women will be evaluated for depression. Women who meet DSM-IV diagnostic criteria for Major Depressive Disorder, as indicated by a structured psychiatric interview (SCID-IV and HAM-D), will then undergo a DEXA scan to determine BMD. Based on the BMD results, depressed women will be divided into two sub-populations: women with normal BMD, and women with low BMD. Women in Group B (depressed women with normal BMD) will be matched by age and body mass index to a control group of healthy, premenopausal, non-depressed women with normal bone mass (Group A). Groups A and B will be followed for 12 months by DEXA determinations every 6 months, measurements of bone turnover every 3 months, and measurements of relevant endocrine parameters every 3 months. Women with depression and low bone mass will enter a 12-month, placebo-controlled, clinical trial where they will be randomized to blind alendronate 70 mg once a week (Group C) or blind placebo once a week (Group D). In addition to alendronate 70 mg once a week, or placebo once a week, women in Groups C and D will also

receive daily 800-1000 mg of elemental calcium and 400 IU of vitamin D. DEXA determinations will be performed at Screening, Month 0, Month 6, and Month 12. Determination of biochemical markers of bone turnover and relevant endocrine parameters to depression will be performed at Months 0, 3, 6, 9 and 12.

Eligibility

Genders Eligible for Study: Female

Accepts Healthy Volunteers Criteria
DEPRESSED WOMEN
Major depression.
Age group 21-45.
Can not have current or past history of schizophrenia, bipolar, or eating disorders.
Not known to have risk of suicide.
No women who may have a contrandication to the use of alendronate, including history (in the past year) of major upper gastrointestinal disease.
HEALTHY CONTROL WOMEN
Absent of current or past major depression or any other DSM-IV diagnosis.
Age group 21-45.
Can not have major organ disease.
ALL WOMEN
Can not be a women in menopausal status.
No pregnant or nursing women.
No women unwilling to use contraceptives, as needed.
No major organ disease.

Expected Total Enrollment: 160

Location and Contact Information

Maryland
National Institute of Mental Health (NIMH), 9000 Rockville Pike Bethesda, Maryland, 20892, United States; Recruiting
Patient Recruitment and Public Liaison Office 1-800-411-1222 prpl@mail.cc.nih.gov
TTY 1-866-411-1010

More Information

Detailed Web Page

Publications

Michelson D, Stratakis C, Hill L, Reynolds J, Galliven E, Chrousos G, Gold P. Bone mineral density in women with depression. N Engl J Med. 1996 Oct 17;335(16):1176-81.

Chrousos GP, Gold PW. The concepts of stress and stress system disorders. Overview of physical and behavioral homeostasis. JAMA. 1992 Mar 4;267(9):1244-52. Review.

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